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# NOTICE OF ALLOWANCE AND FEE(S) DUE

76392

7590

12/30/2008

LAW OFFICE OF SALVATORE ARRIGO 1050 CONNECTICUT AVE. NW 10TH FLOOR WASHINGTON, DC 20036 EXAMINER

BLUMEL, BENJAMIN P

ART UNIT PAPER NUMBER

1648 DATE MAILED: 12/30/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587.082	07/21/2006	Anton Mayr	BN55-PCT-US	6952

TITLE OF INVENTION: PARAMUNITY INDUCERS BASED ON ATTENUATED RABBIT MYXOMA VIRUSES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	03/30/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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## Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450

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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 76392 7590 12/30/2008 Certificate of Mailing or Transmission LAW OFFICE OF SALVATORE ARRIGO I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. 1050 CONNECTICUT AVE. NW 10TH FLOOR WASHINGTON, DC 20036 (Depositor's name (Signature (Date APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE 10/587-082 07/21/2006 BN55-PCT-US 6952 Anton Mavr TITLE OF INVENTION: PARAMUNITY INDUCERS BASED ON ATTENUATED RABBIT MYXOMA VIRUSES APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$0 \$1810 03/30/2009 **EXAMINER** ART UNIT CLASS-SUBCLASS BLUMEL, BENJAMIN P 1648 435-236000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_\_ (enclose an extra copy of this fo Advance Order - # of Copies \_ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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76392 75	590 12/30/2008		EXAM	INER
LAW OFFICE OF SALVATORE ARRIGO 1050 CONNECTICUT AVE. NW			BLUMEL, BENJAMIN P	
			ART UNIT	PAPER NUMBER
10TH FLOOR WASHINGTON, DC 20036			1648 DATE MAILED: 12/30/200	8

## **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 3 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 3 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)		
	10/587,082	MAYR ET AL.		
Notice of Allowability	Examiner	Art Unit		
	BENJAMIN P. BLUMEL	1648		
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this ap or other appropriate communicatio <b>IGHTS</b> . This application is subject	oplication. If not included n will be mailed in due course. <b>THIS</b>		
1. 🔀 This communication is responsive to applicant initiated inte	erview of December 12, 2008.			
2. The allowed claim(s) is/are <u>96-116</u> .				
3. Acknowledgment is made of a claim for foreign priority un a) All b) Some* c) None of the:	- , , , , , ,			
<ol> <li>Certified copies of the priority documents have</li> </ol>				
<ol><li>Certified copies of the priority documents have</li></ol>				
<ol><li>Copies of the certified copies of the priority do</li></ol>	cuments have been received in this	national stage application from the		
International Bureau (PCT Rule 17.2(a)).				
* Certified copies not received:				
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		complying with the requirements		
4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give				
5. CORRECTED DRAWINGS ( as "replacement sheets") mus	st be submitted.			
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached				
1)  hereto or 2) to Paper No./Mail Date				
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of				
Paper No./Mail Date				
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t				
6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT				
Attachment(s)	5. ☐ Notice of Informal I	Potent Application		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftperson's Patent Drawing Review (PTO-948)</li> </ol>				
2.   Notice of Draftperson's Patent Drawing Review (PTO-948)	6.  ☐ Interview Summary Paper No./Mail Da	ate .		
3. Information Disclosure Statements (PTO/SB/08),	7. 🛛 Examiner's Amend	ment/Comment		
Paper No./Mail Date  4.  Examiner's Comment Regarding Requirement for Deposit	8. 🛛 Examiner's Statem	ent of Reasons for Allowance		
of Biological Material	9.			
//BENJAMIN P BLUMEL//				
Examiner, Art Unit 1648				

## **DETAILED ACTION**

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the examiner's amendments made below.

Claims 70-95 are examined on the merits.

# Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: the prior art fails to teach passaging myxomavirus through chorioallantoic membranes of chicken eggs, followed by passaging in Vero monkey kidney cells, then passaging in a binary cell based on a CEF cell fused with a Vero monkey kidney cell, and then passaging back in Vero monkey kidney cells. Wherein, these passaging steps result in an attenuated myxomavirus.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Salvatore J. Arrigo on December 16, 2008.

The application has been amended as follows:

IN THE CLAIMS:

Claims 70-95 are canceled.

96. (New) A method for producing a paramunity inducer comprising:

- (a) isolating a myxomavirus from infected tissue of a rabbit;
- (b) adapting the virus to a permissive cell system;
- (c) passaging the adapted virus in Vero monkey kidney cells;
- (d) passaging the Vero cell passaged virus in a binary cell culture obtained by cell fusion between chicken embryo fibroblast cells and Vero monkey kidney cells;
- (e) passaging the binary cell passaged virus in Vero monkey kidney cells; and
- (f) selecting an attenuated myxomavirus that induces paramunity.
- 97. (New) The method of claim 96, wherein the adaptation of the virus to a permissive cell system comprises culturing the virus on a chorioallantoic membrane of an incubated chicken egg.
- 98. (New) The method of claim 96, wherein the virus is passaged at least 80 passages in Vero monkey kidney cells.
- 99. (New) The method of claim 98, wherein the virus is passaged at least 120 passages in Vero monkey kidney cells.
- 100. (New) The method of claim 99, wherein the virus is passaged at least 150 passages in Vero Monkey kidney cells.

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Art Unit: 1648

101. (New) The method of claim 96, wherein the virus is passaged at least 10 passages in the binary cell culture.

- 102. (New) The method of claim 101, wherein the virus is passaged at least 25 passages in the binary cell culture.
- 103. (New) The method of claim 102, wherein the virus is passaged 50 passages in the binary cell culture.
- 104. (New) The method of claim 96, wherein the attenuated myxomavirus is inactivated with beta-propiolactone.
- 105. (New) The method of claim 104, wherein the beta-propiolactone is at a concentration of 0.01%-1%.
- 106. (New) A method for producing a paramunity inducer comprising:
  - (a) isolating a myxomavirus from infected tissue of a rabbit;
  - (b) adapting the virus to a permissive cell system;
  - (c) passaging the adapted virus in Vero monkey kidney cells;
  - (d) passaging the Vero cell passaged virus in a binary cell culture obtained by cell fusion between chicken embryo fibroblast cells and Vero monkey kidney cells;
  - (e) passaging the binary cell passaged virus in Vero monkey kidney cells; and
  - (f) selecting to generate an attenuated myxomavirus that induces paramunity and has lost the receptor properties of one or more myxomavirus interferon receptor, one or more myxomavirus tumor necrosis factor receptor, and one or more myxomavirus interleukin receptor.

107. (New) The method of claim 106, wherein the attenuated myxomavirus has lost the receptor properties of the myxomavirus cytokine receptors IFNα-R, IFNγ-R, TNF-R, IL-1-R, IL-2-R, IL-6-R, and IL-12-R.

108. (New) The method of claim 106, wherein the adaptation of the virus to a permissive cell system comprises culturing the virus on a chorioallantoic membrane of an incubated chicken egg.

109. (New) The method of claim 106, wherein the virus is passaged at least 80 passages in Vero monkey kidney cells.

110. (New) The method of claim 109, wherein the virus is passaged at least 120 passages in Vero monkey kidney cells.

111. (New) The method of claim 110, wherein the virus is passaged at least 150 passages in Vero monkey kidney cells.

112. (New) The method of claim 106, wherein the virus is passaged at least 10 passages in the binary cell culture.

113. (New) The method of claim 112, wherein the virus is passaged at least 25 passages in the binary cell culture.

114. (New) The method of claim 113, wherein the virus is passaged 50 passages in the binary cell culture.

115. (New) The method of claim 106, wherein the attenuated myxomavirus is inactivated with beta-propiolactone.

116. (New) The method of claim 115, wherein the beta-propiolactone is at a concentration of 0.01%-1%.

## IN THE SPECIFICATION:

Replace the existing title with the following:
--PARAMUNITY INDUCERS BASED ON ATTENUATED RABBIT MYXOMA
VIRUS--

#### Conclusion

Claims 96-116 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/ Examiner Art Unit 1648

/Bruce Campell/ Supervisory Patent Examiner, Art Unit 1648